

Tobacco Cessation: A Quality Improvement Project Using the 5 A's Model

By

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Tobacco Cessation: A Quality Improvement Project Using the 5 A's Model

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Abstract

TOBACCO CESSATION: A QUALITY IMPROVEMENT PROJECT USING THE 5 A'S MODEL

Background: Tobacco use remains the leading preventable cause of death, disease, and disability in the United States. Current statistics show that approximately one in five American adults continue to smoke regularly. Tobacco smoking is responsible for approximately 480,000 premature deaths in the U.S. and over \$300 billion each year in health care costs and productivity losses. Primary care providers have an excellent opportunity to help facilitate tobacco cessation with their patients. There are well-accepted and evidenced-based tobacco cessation tools in the literature that have proven to be effective in the clinical setting. Unfortunately, data suggest that consistent cessation treatments are not being provided.

Project Aim: The aim of this quality and process improvement project was to address the inconsistency of usual care in tobacco cessation interventions within the primary care setting by implementing the 5 A's model. Widely viewed as the gold standard guideline in addressing tobacco cessation and treatment, the 5 A's are ask, advise, assess, assist, and arrange.

Methods: The project took place at a nurse practitioner-based community center that provides primary care services. A pre-intervention questionnaire was administered to six nurse practitioner providers to assess baseline data regarding their current practice with facilitating tobacco cessation among patients. Education about the 5 A's model and the plan for implementation was then provided to the providers and clinic staff by the Project Director during a staff in-service. One month following this intervention, the questionnaire was re-administered. The main outcome of interest was provider adherence to the elements of the 5 A's model, which was measured by the pre- and post-intervention questionnaire.

Results: Participants in the educational in-service revealed a high degree of baseline familiarity with the harms of tobacco and importance of treatment. Improvement was seen in staff familiarity with the 5 A's model and implementation plan, as well as documentation and coding of tobacco use and dependence after the in-service. Six providers completed the pre-intervention questionnaire and three providers completed the post-intervention questionnaire. In 10 of the questionnaire items, the post-intervention weighted averages increased while in nine of the questionnaire items the post-intervention weighted averages decreased. There were four questionnaire items where the weighted averages were the same before and after. Overall, there was a slight positive shift when comparing the weighted averages from the pre-intervention questionnaire items to the post-intervention questionnaire items. However, it cannot be said that this is statistically significant ($Z=-1.01$, $p=.31$).

Conclusion: While the in-service was effective in increasing staff familiarity with the 5 A's model and plan for implementation, it did not improve provider adherence to the elements of the 5 A's model. However, limited conclusions can be drawn given the project's small sample size, attrition in participants, and methods of statistical analysis.

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Tobacco Cessation: A Quality Improvement Project Using the 5 A's Model

It is common knowledge that tobacco use is a major public health concern both in the United States and worldwide. Tobacco smoking is responsible for approximately 480,000 premature deaths and over \$300 billion each year in health care costs and productivity losses in the U.S. (Jamal et al., 2015). Globally, tobacco use causes upwards of six million deaths per year (Centers for Disease Control and Prevention, 2017). Current statistics show that approximately one in five American adults continue to smoke regularly (Larzelere & Williams, 2012). While it is encouraging to note that the percentage of U.S. adults that smoke has declined from 20.9% in 2005 to 16.8% in 2014 (Jamal et al., 2015), tobacco use remains the leading preventable cause of death, disease, and disability in the U.S. (Jamal et al., 2015; Siu, 2015; Williams et al., 2014). Furthermore, the current cigarette smoking rate of 16.8% remains higher than the goal of $\leq 12\%$ as set by *Healthy People 2020* (Office of Disease Prevention and Health Promotion, 2016).

Primary care providers have a great opportunity to help facilitate tobacco cessation with their patients. The majority of tobacco users visit a clinician on a regular basis and more than 70% of all smokers report that they want to quit (Fiore et al., 2008; Green, 2015; Tong, Strouse, Hall, Kovac, & Schroeder, 2010; Williams et al., 2014). There are well-accepted and evidenced-based tobacco cessation tools in the literature that have proven to be effective in the clinical setting (Williams et al., 2014). Unfortunately, data suggest that consistent cessation treatments are not being provided (Kruger, O'Halloran, Rosenthal, Babb, & Fiore, 2016). This presents what Fiore et al. (2008) describes as a rare confluence of circumstances, where there exists a highly significant health threat that is inconsistently intervened upon by clinicians despite the presence of effective interventions (p. 12). It is arguable that no other health condition can claim

such a disparity.

In 2000, the U.S. Public Health Service (USPHS) released an update of its 1996 clinical practice guideline, which utilized the 5 A's model that served as a framework for treating tobacco use and dependence (Fiore et al., 2000). The 5 A's in this model are ask, advise, assess, assist, and arrange (Fiore et al., 2008). The 5 A's model continues to remain the gold standard of provider interventions for addressing tobacco use and dependence. Recent studies have shown that while providers frequently ask and advise their patients about smoking, they are much less apt to assess smokers' willingness to make a quit attempt, assist in their quit attempt, and arrange for follow-up (Kruger et al., 2016; Tong et al., 2010). Full adherence to the 5 A's model as recommended by the USPHS is critical to give patients the best chance of success at tobacco cessation.

Project Purpose Statement

The purpose of this quality and process improvement project was to address the inconsistency and incompleteness of the usual care in tobacco cessation interventions by formally implementing the 5 A's model in the primary care setting. The question that this project sought to answer was, "In a primary care clinic located in a medically underserved area in the Midwest, does the implementation of the 5 A's model, as compared to usual care, lead to improved rates of asking about tobacco use, advising tobacco users to quit, assessing willingness to make a quit attempt, assisting tobacco users in making a quit attempt, and arranging for follow-up?"

Concepts and Variables

Cigarette smokers make up the majority of tobacco users in the United States; thus, the vast body of literature and research regarding tobacco use is focused on the treatment and

assessment of smoking (Fiore et al., 2008). Understanding the need to address all forms of tobacco use, Fiore et al. (2008) sought to describe interventions in their guideline in a way that broadly encompassed all types of tobacco use. Following their example, this project made every attempt to apply to all forms of tobacco use.

The primary concepts of interest in this project were tobacco, tobacco use, tobacco cessation, and provider adherence. The independent variable in the project was the implementation of the 5 A's model. The dependent variable in the project was adherence to the elements of the 5 A's model. The concepts that make up the 5 A's model are ask, advise, assess, assist, and arrange (Fiore et al., 2008).

Definition of Terms

The Food and Drug Administration (FDA) defines the term “tobacco product” as “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (U.S. Food and Drug Administration, 2015, December 28). New tobacco products are continually being brought into the marketplace, challenging the traditional thought and definition of the term tobacco product. In May of 2016, the FDA issued a final rule extending their regulation to all tobacco products and expanding their definition of what a tobacco product is. Their definition of tobacco products, which also served as the operational definition for this project, includes hookah, e-cigarettes, dissolvables, smokeless tobacco, cigarettes, cigars, roll-your-own tobacco, and pipe tobacco (U.S. Food and Drug Administration, 2016, June 16). Tobacco users, as defined by the Department of Health and Human Services, are those individuals who use any tobacco product other than for religious or ceremonial use on average of four or more times per week within no longer than the past six months (Department of Health and Human Services, 2013). Cessation is defined as “the fact or

process of ending or being brought to an end” (Cessation, 2016). Therefore, tobacco cessation was theoretically defined as the act of ending the use of the above-mentioned tobacco products. The concept of patient adherence is well defined in the literature; however, provider adherence is not. By adapting the definition provided by the World Health Organization (2003) to apply to providers, adherence was defined as the extent to which a person’s behavior corresponds with agreed recommendations. Provider adherence to the 5 A’s was operationally defined and measured by the scores on a pre- and post-intervention questionnaire.

In regard to the 5 A’s model, the concept of ask was defined as identifying and documenting tobacco use at every visit (Fiore et al., 2008). The concept of advise was defined as urging tobacco users to quit in a clear, strong, and personalized manner (Fiore et al., 2008). Assess was defined as determining the patient’s willingness to make a quit attempt (Fiore et al., 2008). Assist was defined as aiding the patient in their cessation attempt by providing counseling and medication if applicable (Fiore et al., 2008). Lastly, arrange was defined as scheduling follow-up contact via telephone or in person or referral to a specialist (Fiore et al., 2008)

Project Importance

This quality and process improvement project was important for a number of different reasons. First and foremost, it represented what was best for the patient. It is well known that there are a considerable amount of health benefits related to tobacco cessation. People that started smoking at an early age but stopped before they were 40 years old have been shown to avoid more than 90% of the excess risk during their next few decades when contrasted against those who continued to smoke (Jha & Peto, 2014).

Second, evidenced-based tobacco cessation interventions have proven to be effective

(Kruger et al., 2016; Siu, 2015; U.S. Department of Health and Human Services, 2014). A recent Cochrane review examined 42 trials conducted between 1972 and 2012 that included over 31,000 smokers with the purpose of assessing the effectiveness of advice from physicians in promoting smoking cessation. Brief advice versus no advice demonstrated a significant increase in quit rates (Stead et al., 2013). In regard to the 5 A's model, delivery of the full 5 A's was associated with greater use of cessation treatments (Kruger et al., 2016).

Third, smoking cessation treatment is considered the most cost-effective preventative intervention available to providers, with the potential cost per life-year-saved to be between \$2000 and \$4000 (Papadakis et al., 2010). On a larger level, as stated previously, tobacco use is responsible for \$300 billion each year in health care costs and productivity losses (Jamal et al., 2015). Nearly 11% or \$22 billion in Medicaid expenditures alone are directly tied to smoking (Centers for Medicare & Medicaid Services, n.d.).

Relevance in Current Literature

The history of the knowledge of the harms of tobacco use dates back to more than 50 years ago (U.S. Department of Health and Human Services, 2014). The first report citing the health consequences of smoking was entitled *Smoking and Health: Report of the Advisory Committee of the Surgeon General of the Public Health Service*, and was released on January 11, 1964, by Dr. Luther L. Terry M.D., the Surgeon General of the United States at the time (U.S. Department of Health and Human Services, 2014). It is clear from the current literature that there is consensus on the view that tobacco use is harmful and cessation interventions are important. In 2014, the United States Preventative Services Task Force (USPSTF) gave a Level A recommendation that providers ask all adults about tobacco use, advise them to stop using tobacco, and provide both behavioral interventions and FDA-approved pharmacotherapy (Siu,

2015). The literature shows that the 5 A's model developed by the USPHS is the most widely recommended approach to engage patients in their tobacco use and thus is considered the gold standard intervention. Unfortunately, as stated before, research shows that full adherence to the 5 A's by providers remains poor.

Literature Review

An Overview of Tobacco Use

Tobacco use is a significant problem that touches every part of the globe. In considering current smoking patterns, approximately 50% of young men and 10% of young women will become smokers worldwide (Jha & Peto, 2014). As these young smokers reach middle and old age, annual tobacco-attributable deaths are predicted to rise from around five million in the year 2010 to more than 10 million in the coming decades (Jha & Peto, 2014). Even more startling is the fact that if current smoking patterns continue, tobacco will be responsible for the deaths of one billion people this century (Jha & Peto, 2014).

Multiple large-scale studies have been conducted to examine the effects on mortality in men and women that began smoking in early adult life and failed to quit (Jha & Peto, 2014). Thun et al. (2013) looked at two historical cohort studies and five pooled contemporary cohort studies in the United States and measured trends in mortality and the absolute and relative risks according to sex and self-reported smoking status. Results revealed that women who were current smokers, compared with women who had never smoked, showed the relative risk of dying from lung cancer was 2.73, 12.65, and 25.66 when looking at the cohorts from the 1960's, 1980's, and contemporary cohorts respectively (Thun et al., 2013). Furthermore, among men age 55 to 74 years of age and women 60 to 74 years of age, current smokers had an all-cause mortality of at least three times as high as those who had never smoked (Thun et al., 2013).

The year 2014 marked 50 years since the first Surgeon General's report on the health hazards of smoking (U.S. Department of Health and Human Services, 2014). Over the course of those 50 years, significant progress has been made including an overall decline of smoking largely due to tobacco control efforts (U.S. Department of Health and Human Services, 2014). Despite this progress, much work remains to be done. Interestingly, smokers today have a higher risk for lung cancer and chronic obstructive pulmonary disease than smokers did when the first report was published in 1964 (U.S. Department of Health and Human Services, 2014). While specific estimates of economic consequences secondary to smoking tend to vary slightly from source to source, the consensus is that the financial burden is staggering. It is estimated that the annual costs related to smoking in the United States ranges from \$289 billion to \$333 billion (U.S. Department of Health and Human Services, 2014).

While cigarette smoking remains the most common form of tobacco consumption, surveys of trends in tobacco use point toward the rise in use of multiple tobacco products, particularly in young adults (U.S. Department of Health and Human Services, 2014). One of the fastest growing tobacco products on the market, especially among young adults, is electronic cigarettes or e-cigarettes. Between 2011 and 2012, the percentage of U.S. middle and high school students who used e-cigarettes more than doubled (U.S. Department of Health and Human Services, 2014). In high school students alone, e-cigarette use grew by 900% between 2011 and 2015. As of 2014, e-cigarette use surpassed conventional cigarette use among youth (U.S. Department of Health and Human Services, 2016).

Support for the 5 A's Model

As previously stated, the majority of tobacco users visit a clinician on a regular basis (Fiore et al., 2008) and 70% of all smokers report that they want to quit (Green, 2015; Tong et

al., 2010; Williams et al., 2014). While the proportion of smokers using evidence-based treatments to aid in their quit attempts is rising, most smokers continue to make unaided quit attempts (Fiore et al., 2008). This is an unfortunate fact considering the research shows that smokers who use an evidence-based counseling or medication treatment to quit are significantly more likely to be successful when compared to those not using such aids (Fiore et al., 2008).

The 5 A's model, first outlined in 1996, was developed by the U.S. Public Health Service as a clinical practice guideline to be used by providers in treating tobacco use and dependence (Fiore et al., 1996). This model developed by Fiore et al. (2008) is highly regarded and widely viewed as the gold standard guideline in addressing tobacco cessation and treatment in clinical settings (Papadakis et al., 2010). Kruger et al. (2016) sought to examine the extent to which delivery of the 5 A's affected patients' actions on the treatment recommendations. After examining data from the 2009 to 2010 National Adult Tobacco Survey, Kruger et al. (2016) found that patients who received the 5 A's intervention were more likely to use the recommended counseling and medication in aiding their cessation attempts.

Quinn et al. (2009) assessed the effectiveness of the 5 A's model in nine health maintenance organizations (HMOs) by looking at data from the HMO's Investigating Tobacco (HIT) study. The HIT study was conducted by the Cancer Research Network, which is an initiative funded by the National Cancer Institute to support and facilitate cancer research (Wagner et al., 2005). In their analysis, Quinn et al. (2009) found that smokers who were assisted in their quit attempt through the offering of pharmacotherapy and referral to classes or counseling were more likely to quit when compared to those who were not offered pharmacotherapy or a referral to classes or counseling.

Aveyard, Begh, Parsons, and West (2012) examined the effectiveness of two key

components of the 5 A's model, advice to quit and offering assistance to quit. Randomized trials from the Cochrane Review of physician advice for smoking cessation were included in their analysis and combined using the Mantel-Haenszel method of meta-analysis (Aveyard et al., 2012). Specific data on quit attempts and quit success were extracted. In the studies included, advice to quit compared to no intervention increased the frequency of quit attempts and their success, as well as increased long-term abstinence by 47% (Aveyard et al., 2012). Two studies showed that combining nicotine replacement therapy with advice to quit smoking doubled abstinence rates (Aveyard et al., 2012).

Provider Adherence to the 5 A's

Despite the research supporting the effectiveness of the 5 A's model, many providers fail to deliver all of the components (Kruger et al., 2016; Tong et al., 2010; Williams et al., 2014). In a recent study, Tong et al. (2010) surveyed 2,804 subjects from seven different health professional groups including primary care physicians, emergency medicine physicians, psychiatrists, registered nurses, dentists, dental hygienists, and pharmacists. Results showed that most providers report asking and advising about smoking, but less often assess smokers' interest in quitting, assisting with quit attempts, and arranging follow-up (Tong et al., 2010). Tremblay, Cournoyer, and O'Loughlin (2009) found similar results when surveying health professionals. Respondents to the survey reported higher rates of asking patients about smoking status and advising them to quit than they did assessing readiness to quit, assisting in quit attempts, and arranging for follow-up (Tremblay et al., 2009). Williams et al. (2014) looked specifically at documentation of the 5 A's in the electronic medical record. In a survey of the electronic medical records of 200 smokers, only 2% of patients had a documented follow-up plan (Williams et al., 2014).

Kruger et al. (2016) sought to assess provider adherence to four of the 5 A's: ask, advise, assist, and arrange. A convenience sample of 1,253 primary care providers were questioned using a web-based panel survey regarding the extent to which they ask, advise, assist, and arrange. The study found that while the vast majority of providers asked about tobacco use, advised patients to quit tobacco, and assisted the patient in their quit attempt, less than half reported that they consistently scheduled a follow-up visit (Kruger et al., 2016).

The literature identifies multiple barriers that stand in the way of clinicians' assessment and treatment of tobacco users (Fiore et al., 2008). These barriers include knowledge deficits regarding how to identify tobacco users quickly and easily, what treatments to offer, how treatments are offered, and the effectiveness of the various treatments (Fiore et al., 2008). Furthermore, providers cite inadequate clinic or institutional support in providing treatment for tobacco use and limited time and reimbursement (Fiore et al., 2008). This highlights the notion that effective tobacco intervention is best facilitated through the contributions of both the individual clinician and the systems and resources surrounding them (Fiore et al., 2008).

Theoretical Framework

There have been numerous theories and frameworks that have been developed for use in quality improvement. One of the most notable and widely used frameworks, and the one that served as the overarching framework to guide this project, is the Plan-Do-Study-Act (PDSA) cycle. Also known as the Deming cycle after its originator, the PDSA cycle got its start in industry in the 1950s as a tool for quality improvement (Moen & Norman, 2010). Frequently applied to the healthcare setting, the PDSA cycle provides an iterative approach to testing small-scale interventions with the ability to rapidly assess and obtain feedback in order to make necessary changes moving forward (Taylor et al., 2014).

The first step in the PDSA cycle is plan, which involves identifying a goal or a purpose, formulating a theory, determining outcomes, and putting a plan into action (The W. Edwards Deming Institute, 2016). As evident in the literature review, tobacco use is a highly significant health threat that is inconsistently intervened upon by clinicians despite the presence of effective interventions (Fiore et al., 2008). The identification of this significant gap in care led to the plan for this project to formally implement the 5 A's model in an outpatient clinic setting, measuring provider adherence to the 5 A's model one month before and one month after the intervention. The decision was made to measure provider adherence rather than conduct an in-depth chart review in order to protect patient privacy and to ensure feasibility of the project. Do is the second step in the PDSA cycle, which involved implementing the components of the plan (The W. Edwards Deming Institute, 2016). After the plan was implemented, the third step was to study. During the study phase of the cycle, an analysis of the data was done and the results were compared to the baseline data and the predictions that were made (Institute for Healthcare Improvement, 2017). The last stage in the PDSA framework is act, which involves integrating the lessons learned throughout the process and determining modifications that need to be made in the future (Institute for Healthcare Improvement, 2017; The W. Edwards Deming Institute, 2016). Results of the project and areas for improvement were shared with the clinic providers and staff, and recommendations for future study were made.

The 5 A's model served as the guiding framework for the intervention portion of this project. While the 5 A's model has been widely used in a variety of primary care interventions for different behaviors, its origins can be traced back to tobacco cessation (Dosh et al., 2005). First developed by the National Cancer Institute as a guide for physician intervention in smoking cessation, the original model contained 4 A's: ask, advise, assist, arrange (Glynn & Manley,

1989; Whitlock, Orleans, Pender, & Allan, 2002). In 2000, the U.S. Public Health Service (USPHS) released a clinical practice guideline regarding smoking cessation that utilized the 5 A's model (Fiore et al., 2000; Quinn et al., 2009). The 5 A's that served as the intervention framework of this project are ask, advise, assess, assist, and arrange (Fiore et al., 2008).

Author's Assumptions

Based upon a review of the literature, it was assumed that an examination of the project sample's usual care would reveal an incomplete adherence to the full 5 A's model. Furthermore, it was assumed that baseline knowledge of the 5 A's model and the plan for implementation would be limited. If these assumptions proved to be true, it could be posited that a structured, systems-based quality improvement project tailored towards the specific project sample setting would result in greater provider and clinic adherence to the 5 A's model, as well as familiarity with the 5 A's model and implementation plan.

Project Methods

Project Design and Rationale

This project consisted of an evidence-implementing quality and process improvement design, intended to educate clinic providers and staff on the 5 A's model and ultimately to increase provider adherence to the elements of the 5 A's model. Prior to beginning the project, the Project Director submitted the final project proposal to the institutional review board (IRB) at the University of Kansas Medical Center for review. After IRB review, the project was determined to be a quality improvement project, as it did not contain research involving human subjects (see Appendix A). Permission to implement the project was then obtained from the director of clinical services at the clinic site (see Appendix B).

Project Setting

This project took place in a primary care clinic in a medically underserved area in the Midwest. The clinic largely serves English- and Spanish-speaking residents of Wyandotte and Johnson counties in the state of Kansas and is in collaboration with a local school of nursing, school of health professions, and school of medicine. The clinic's patient population ranges from birth to the elderly and from the uninsured to those with government or private health insurance coverage.

Project Sample and Selection Process

The sample that was used for this project were nurse practitioners who practice in the above-mentioned clinic. Given that this was a quality improvement project focused on one specific clinic, a non-probability convenience sampling method was used for the selection process due to the small sample size. There were six nurse practitioner providers who were practicing in the clinic at the time of the project. Each of the six providers were invited to participate in the project, with knowledge that they would not be rewarded or penalized for their participation or lack of participation. A letter of consent to participate in the project was sent to the providers and returned to the Project Director (see Appendix C). Additional clinic staff were included in the in-service education and participated in the implementation of the intervention; however, they did not contribute directly to the measured outcome of the project.

The 5 A's Intervention

After gaining quality improvement determination through the IRB and obtaining permission to implement the project at the clinic, the Project Director met with the clinic manager to review current processes and workflow in order to assess usual care in regard to the baseline degree of delivery of the 5 A's. This information was then compared to the 5 A's model

as outlined in the guideline by Fiore et al. (2008). The Project Director then developed a plan for how to implement the 5 A's model, tailored to the specific project site. On July 11th 2017, the Project Director conducted a lunch in-service where baseline data as well as education on the 5 A's model and the plan for implementation of the intervention was discussed. A survey to assess staff understanding of the harms of tobacco, knowledge of the 5 A's model, plan for implementation of the 5 A's model, and fluency with documentation and coding as it relates to tobacco dependence and treatment was administered before and after the in-service. The components of the 5 A's model as outlined below were designed to be brief and require three minutes or less to implement (Fiore et al., 2008).

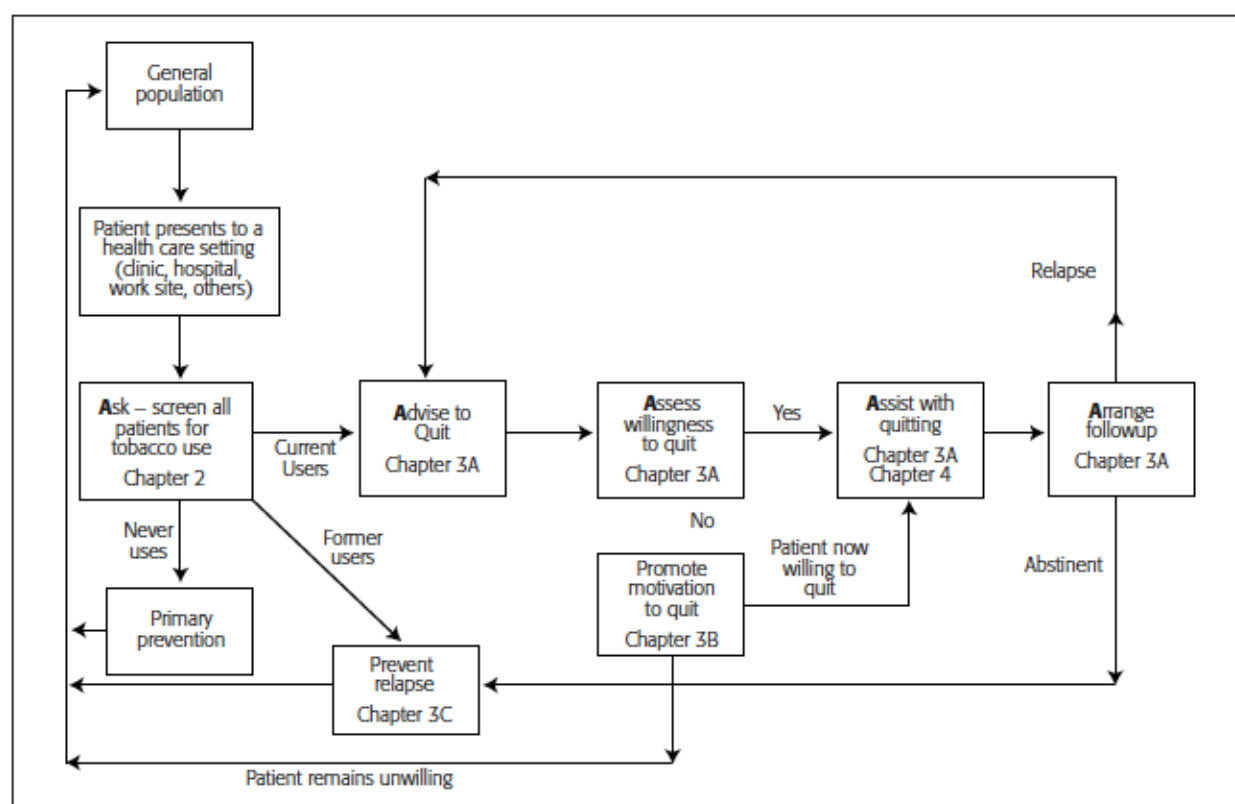


Figure 1. Model for treatment of tobacco use and dependence (Fiore et al., 2008)

Ask. The first step in an effective tobacco cessation intervention is identifying tobacco users. Therefore, it is imperative to “Identify and document tobacco use status for every patient

at every visit” (Fiore et al., 2008). The previous vital signs rooming form used by the clinic assessed smoking status and smoking amount; however, it did not address other forms of tobacco. In order to adhere to the guideline, the nomenclature was changed to “tobacco use” and “tobacco amount.” Choices for documenting tobacco use included “Current,” “Former,” or “Never” (see Appendix D).

Advise. Tobacco users should be urged to quit in a clear, strong, and personalized manner (Fiore et al., 2008). During the educational in-service, the clinic providers and staff were given examples of scripting and wording to use when counseling their patients on the importance of cessation such as the statements below.

Clear—“It is important that you quit smoking (or using chewing tobacco) now, and I can help you.” “Cutting down while you are ill is not enough.” “Occasional or light smoking is still dangerous.” *Strong*—“As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you.” *Personalized*—“Continuing to smoke makes your asthma worse, and quitting may dramatically improve your health.” Quitting smoking may reduce the number of ear infections your child has” (Fiore et al., 2008).

Assess. The guideline recommends that every tobacco user should be assessed for their willingness to make a quit attempt (Fiore et al., 2008). This was accomplished by adding “ready to quit” with the options of “yes,” “no,” or “N/A” on the intake form next to the tobacco use vital sign. Having the documentation of the patient’s willingness to make a quit attempt on the intake form informed the provider of where the patient stood in their willingness to quit and guided the provider on the approach they took in their counseling.

Assist. During the in-service, education was given to providers and staff on how to

approach both the patient willing to make a quit attempt and the patient unwilling to make a quit attempt. For the patient willing to make a quit attempt, Fiore et al. (2008) recommend that providers aid patients in their quit attempts by assisting them with the development of a quit plan. Staff were familiarized with and encouraged to use the mnemonic STAR, which instructs patients to: **S**et a quit date, **T**ell family, friends and coworkers, **A**nticipate challenges, and **R**emove tobacco products from the environment (Fiore et al., 2008). Brief and practical counseling was also discussed for items such as striving for total abstinence, discussing past quit experiences, and strategizing and planning for anticipated challenges. Additional supplementary material and tobacco quit lines were reviewed, including the KanQuit hotline and the use of smokefreeTXT on mobile phones. Lastly, the guideline recommends the use of medication unless contraindicated (Fiore et al., 2008). The seven FDA-approved medications for treating tobacco use include bupropion SR, varenicline, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, and the nicotine patch (Fiore et al., 2008). These seven medications were briefly reviewed and a pharmacologic product guide was distributed (see Appendix E). During the baseline assessment of the clinic, it was identified that access to medication would be a major barrier for a large portion of the patient population. Knowing this, staff were provided with education on various programs available to patients on Medicare, Medicaid, private insurance, and those who are uninsured.

For the patient unwilling to make a quit attempt, the guideline calls for providers to promote motivation to quit using a directive, patient-centered counseling intervention (Fiore et al., 2008). Evidence shows that motivational interviewing (MI) leads to increased future quit attempts (Fiore et al., 2008). The four general principles of MI were reviewed, which include expressing empathy, developing discrepancy, rolling with resistance, and supporting self-

efficacy (Fiore et al., 2008). Examples of MI strategies related to tobacco cessation were discussed and demonstrated during the in-service using a role-playing activity with staff (see Appendix F).

Arrange. Fiore et al. (2008) recommend follow-up contact to be arranged either in person or via telephone with the first contact to be made soon after the quit date, preferably during the first week. During the in-service, the plan for arranging follow-up was discussed which involved the medical assistants calling the patient one to two weeks after the quit date. Content for the follow up visits was reviewed, which included focusing on identifying problems encountered, assessing medication use if prescribed, and anticipating challenges in the immediate future (Fiore et al., 2008). A second follow-up is recommended one month after the quit date (Fiore et al., 2008). Given that many patients would not realistically be able to present back specifically for tobacco cessation follow-up, providers were instructed to follow up with patients on their next routine visit. Lastly, staff were encouraged to treat patients' tobacco use as a chronic disease and identify it as such in the electronic medical record (EMR) (Fiore et al., 2008).

Documentation in Electronic Medical Record

EMRs have been shown to hold the potential to improve the quality and efficiency of patient care (Boyle, Solberg, & Fiore, 2014). Utilizing the EMR to document and track patient information regarding their tobacco use and progress toward quitting represents a systems level change that may increase the provider adherence to recommended guidelines, such as the 5 A's model (Boyle et al., 2014). After consulting with the director of clinical services at the clinic, the Program Director built an EMR tool for providers to use when documenting tobacco use and dependence as well as the treatment provided. This tool addressed each element of the 5 A's

model in its entirety as recommended by the guideline, and served as a standardized way for the providers to document these elements with patients at every visit.

Tobacco Treatment	Tobacco Treatment
Tobacco use status: «Tobacco use status...»	Tobacco use status: «Tobacco use status...»Current
Tobacco type: «Tobacco type...»	Tobacco type: «Tobacco type...»Cigarettes
Tobacco amount: free form typing	Tobacco amount: 1ppd
Advise: Advised to quit	Advise: Patient was advised to quit in a clear, strong, and personalized manner.
Willing to make quit attempt: yes no	Willing to make quit attempt: yes no
Assisted in their quit attempt by: «Medication...» Quit plan KanQuit	Assisted in their quit attempt by: «Medication...»Varenicline, Helping patient develop a quit plan (setting a date, discussing previous quit attempts, withdrawal symptoms, worries about cessation, strategies to quit smoking), KanQuit referral
Unwilling to quit: Motivational interviewing	Unwilling to quit: Motivational interviewing
Quit date: free form typing	Quit date: 7/11/17
Follow up: free form typing	Follow up: Phone call follow up in 1 week. Address tobacco use at next appt.
Amount of time spent counseling patient: free form typing	Amount of time spent counseling patient: 8min

Figure 2. EMR documentation tool.

Data Collection

On Tuesday July 11th, the Project Director conducted a lunch in-service at the project site. Prior to beginning the in-service, staff members were given a four-item pre-survey to assess their baseline knowledge of the harms of tobacco and importance of treatment, familiarity with the 5 A's model and the plan for implementation, and familiarity with documentation and coding of tobacco related disorders and treatment (see Appendix G). The items on the pre-survey used a four-point Likert scale to measure familiarity, with the options of very familiar, somewhat familiar, slightly familiar, and not at all familiar. The in-service consisted of a PowerPoint presentation delivered by the Project Director that covered the following objectives.

1. Understand the importance of addressing tobacco use and dependence.
2. Understand the elements of the 5 A's model.
3. Understand the plans to implement the 5 A's model at SCHC.
4. Understand documentation and coding as it relates to treatment of tobacco use and dependence.

After a brief question and answer period following the presentation, staff members were given

the same survey to assess their understanding of the above-mentioned objectives.

The outcomes of interest for this quality and process improvement project were provider adherence to the 5 A's model. Measurement of these objectives was accomplished by administering an online pre-intervention questionnaire to providers, followed by the implementation of the 5 A's model and administration of an online post-intervention questionnaire one month after the implementation of the 5 A's model. The questionnaire that was utilized for both pre- and post-intervention assessment was based upon the questionnaire developed by Tremblay et al. (2009) to assess providers' adherence to 5 A's cessation counseling practices (see Appendix H).

To assess provider adherence to asking about tobacco use status, a series of seven items were evaluated. The questions were as follows:

During the past month, for what proportion of your patients did you ascertain tobacco use status in each of the following patient groups: (a) patients on a first visit; (b) patients with tobacco-related symptoms or diseases; (c) patients who were tobacco users at their last visit; (d) patients without tobacco-related symptoms or diseases; (e) adolescents (age 13-19 years); (f) patients in general, and (g) during the past month, for what proportion of your patients who use tobacco did you indicate their tobacco use status in the patient's chart? (Tremblay et al., 2009, p. 1335).

To assess provider adherence to advising tobacco users to quit, the following single question was asked: "During the past month, for what proportion of your patients who use tobacco did you advise the patient to stop using tobacco?" (Tremblay et al., 2009, p. 1336). To assess provider adherence to assessing readiness to quit, the following single question was asked: "During the past month, for what proportion of your patients who use tobacco did you assess readiness to

quit?” (Tremblay et al., 2009, p. 1336). Questions regarding provider self-reported rates of assisting tobacco users in their quit attempts were divided between patients that were ready to quit and patients that were not ready to quit. For patients ready to quit, a series of seven items were evaluated. The questions were as follows:

During the past month, for what proportion of your patients who use tobacco and who were preparing to quit did you: (a) ascertain the amount of tobacco used per day, (b) discuss previous quit attempts, (c) discuss withdrawal symptoms, (d) discuss worries about cessation, (e) discuss strategies to quit, (f) advise setting a quit date, and (g) recommend/prescribe nicotine replacement medications (Tremblay et al., 2009, p. 1336).

For patients not ready to quit, a series of five items were evaluated. The questions were as follows:

During the past month, for what proportion of your patients who use tobacco and who were not ready to quit did you: (a) discuss the effects of tobacco use on health, (b) discuss their perceptions of the pros and cons of tobacco use, (c) discuss their perceptions of the pros and cons of quitting, (d) express concerns about their tobacco use, and (e) discuss the effects of secondhand smoke on the health of relatives and friends? (Tremblay et al., 2009, p. 1336).

Questions regarding provider self-reported rates of arranging for follow-up were divided between tobacco users ready to quit and tobacco users not ready to quit. For tobacco users ready to quit, the following single-item indicators were asked:

(a) During the past month, for what proportion of your patients who use tobacco and who were preparing to quit did you arrange an appointment or telephone call 1 to 2 weeks after the quit date? (b) During the past month, for what proportion of your patients who

use tobacco and who were preparing to quit did you refer to a tobacco cessation resource in the community such as [KanQuit], a smoking cessation center, or a health professional with expertise in cessation? (Tremblay et al., 2009, p. 1336).

Lastly, for tobacco users who are not ready to quit, the following question was asked: “During the past month, for what proportion of your patients who use tobacco and who were not ready to quit did you arrange an appointment specifically to discuss quitting?” (Tremblay et al., 2009, p. 1336). The questionnaire used a 5-point Likert scale with the options of “all/almost all, more than half, about half, less than half, and few/none of patients” (Tremblay et al., 2009, p. 1336).

Data Analysis

The pre- and post-intervention questionnaires were made available to the providers through the online survey development site SurveyMonkey. Results from the questionnaires were then uploaded into Microsoft Excel to be analyzed, as well as the software program IBM SPSS Statistics. The questionnaires were anonymous and thus were unable to be paired for each respondent. Furthermore, while all six providers completed the pre-intervention questionnaire, only three providers completed the post-intervention questionnaire. For these reasons, the results were compiled and averaged giving a representation of the group of providers as a whole. The anonymous pre- and post-survey that was given before and after the in-service was administered on one sheet of paper, allowing for the subjects to be paired.

The Project Director scheduled a consultation with a faculty member of the Department of Biostatistics at the University of Kansas Medical Center for assistance with statistical analysis. It was recommended by the statistician that the Wilcoxon signed-rank test be used to interpret the data. The Wilcoxon signed-rank test is a non-parametric test that allows the researcher to analyze matched-pair data based on differences (Woolson, 2007). For this test, the null

hypothesis is that the differences of the pairs have a distribution of zero (Woolson, 2007). The positive and negative values are totaled and it is determined whether a positive or negative shift is present. In addition to the Wilcoxon signed-rank test, the percentage change was calculated for each item on the questionnaire allowing for a basic descriptive statistical analysis and interpretation of the data.

Results

In-Service Survey

A total of 11 respondents filled out the pre- and post-intervention survey before and after the staff in-service. Participants were asked to rank their familiarity with each item using a four-point weighted Likert scale (4 = *very familiar*, 3 = *somewhat familiar*, 2 = *slightly familiar*, 1 = *not at all familiar*). The first question on the four-item survey was, “How familiar are you with the harms of tobacco and the importance of addressing tobacco use and dependence?” Table 1 displays a descriptive statistical overview of the data. The weighted mean for the pre-survey responses was 3.73 and the weighted mean for the post-survey responses was 3.91, with standard deviations of .47 and .30 accordingly. While the Wilcoxon signed-rank test does show

Table 1. *Familiarity with Harms of Tobacco and Importance of Treatment*

	N	Mean	Std. Deviation	Minimum	Maximum
Pre-Survey	11	3.7273	.46710	3.00	4.00
Post-Survey	11	3.9091	.30151	3.00	4.00

Table 2. *Familiarity with Harms of Tobacco and Importance of Treatment - Ranks*

		N	Mean Rank	Sum of Ranks
Post-Survey – Pre-Survey	Negative Ranks	0 ^a	.00	.00
	Positive Ranks	2 ^b	1.50	3.00
	Ties	9 ^c		
	Total	11		

a. Post-Survey < Pre-Survey b. Post-Survey > Pre-Survey c. Post-Survey = Pre-Survey

a slight positive shift (post-survey > pre-survey), it cannot be said that there was a statistically significant change from the pre-survey scores to the post-survey scores ($Z=-1.41$, $p=.157$).

The second question was “How familiar are you with the 5 A’s model for tobacco cessation.” Table 3 displays a descriptive statistical overview of the data. The weighted mean for the pre-survey responses was 2.64 and the weighted mean for the post-survey responses was 3.81, with standard deviations of 1.03 and .40 respectively. The Wilcoxon signed-rank test

Table 3. *Familiarity with the 5 A's Model for Tobacco Cessation*

	N	Mean	Std. Deviation	Minimum	Maximum
Pre-Survey	11	2.6364	1.02691	1.00	4.00
Post-Survey	11	3.8182	.40452	3.00	4.00

Table 4. *Familiarity with the 5 A's Model for Tobacco Cessation - Ranks*

	N	Mean Rank	Sum of Ranks
Post-Survey – Pre-Survey Negative Ranks	0 ^a	.00	.00
Positive Ranks	9 ^b	5.00	45.00
Ties	2 ^c		
Total	11		

a. Post-Survey < Pre-Survey b. Post-Survey > Pre-Survey c. Post-Survey = Pre-Survey

demonstrates that post-survey scores were statistically significantly higher than the pre-survey scores ($Z=-2.81$, $p=.005$).

The third question on the survey was “How familiar are you with the plans to implement the 5 A’s model at SCHC?” Table 5 displays a descriptive statistical overview of the data. The weighted mean for the pre-survey responses was 2.09 and the weighted mean for the post-survey responses was 3.45, with standard deviations of 1.14 and .522 respectively. The Wilcoxon

Table 5. *Familiarity with Plans to Implement 5 A's Model at SCHC*

	N	Mean	Std. Deviation	Minimum	Maximum
Pre-Survey	11	2.0909	1.13618	1.00	4.00
Post-Survey	11	3.4545	.52223	3.00	4.00

Table 6. *Familiarity with Plans to Implement 5 A's Model at SCHC - Ranks*

	N	Mean Rank	Sum of Ranks
Post-Survey – Pre-Survey Negative Ranks	0 ^a	.00	.00
Positive Ranks	9 ^b	5.00	45.00
Ties	2 ^c		
Total	11		

a. Post-Survey < Pre-Survey b. Post-Survey > Pre-Survey c. Post-Survey = Pre-Survey

signed-rank test demonstrates that post-survey scores were statistically significantly higher than the pre-survey scores ($Z=-2.71$, $p=.007$).

The fourth and final question on the in-service survey was “How familiar are you with documentation and coding as it relates to treatment of tobacco use and dependence?” Table 7 displays a descriptive statistical overview of the data. The weighted mean for the pre-survey responses was 2.00 and the weighted mean for the post-survey responses was 3.09, with standard deviations of 1.00 and .94 respectively. The Wilcoxon signed-rank test demonstrates that post-

Table 7. *Familiarity with Documentation and Coding of Tobacco Use and Dependence*

	N	Mean	Std. Deviation	Minimum	Maximum
Pre-Survey	11	2.0000	1.00000	1.00	4.00
Post-Survey	11	3.0909	.94388	2.00	4.00

Table 8. *Familiarity with Documentation and Coding of Tobacco Use and Dependence - Ranks*

	N	Mean Rank	Sum of Ranks
Post-Survey – Pre-Survey Negative Ranks	0 ^a	.00	.00
Positive Ranks	9 ^b	5.00	45.00
Ties	2 ^c		
Total	11		

a. Post-Survey < Pre-Survey b. Post-Survey > Pre-Survey c. Post-Survey = Pre-Survey

survey scores were statistically significantly higher than the pre-survey scores ($Z=-2.76$, $p=.006$).

Provider Questionnaire

All six of the providers completed the pre-intervention questionnaire; however, only three of the providers completed the post-intervention questionnaire. Unfortunately, the manner in which the questionnaire was delivered did not allow for the Project Director to match the pre- and post-questionnaires. Due to the unequal sample sizes and the inability to match the questionnaires, the results were compiled and averaged giving a representation of the group of providers as a whole. To analyze the data using the Wilcoxon signed-rank test, the pre-intervention weighted-average for each item on the questionnaire was paired with the post-intervention weighted-average. The questionnaire had a total of eight questions, with some containing a subset of multiple items. In total, there were 23 items on the questionnaire and thus 23 “pairs” were used in the Wilcoxon signed-rank test. Table 9 displays a descriptive statistical overview of the data.

Table 9. *Provider Adherence to the 5 A's Model*

	N	Mean	Std. Deviation	Minimum	Maximum
Pre-Intervention	23	4.0957	.98867	1.83	5.00
Post-Intervention	23	4.3061	.79680	1.67	5.00

Table 10. *Provider Adherence to the 5 A's Model - Ranks*

		N	Mean Rank	Sum of Ranks
Post-Intervention – Pre-Intervention	Negative Ranks	9 ^a	7.78	70.00
	Positive Ranks	10 ^b	12.00	120.00
	Ties	4 ^c		
	Total	23		

a. Post-Intervention < Pre-Intervention

b. Post-Intervention > Pre-Intervention

c. Post-Intervention = Pre-Intervention

The mean for the weighted averages of the pre-intervention questionnaire items was 4.10 and the mean for the weighted averages of the post-intervention questionnaire items was 4.31. They had

standard deviations of .99 and .80 respectively. Table 10 shows the Wilcoxon signed-rank test for the data. In ten questionnaire items, the post-intervention weighted averages increased while in nine questionnaire items the post-intervention weighted averages decreased. There were four questionnaire items where the weighted averages were the same before and after. Overall, there was a slight positive shift when comparing the weighted averages from the pre-intervention questionnaire items to the post-intervention questionnaire items. However, it cannot be said that this is statistically significant ($Z=-1.01$, $p=.31$).

The largest positive percentage change was in regard to recommending and prescribing nicotine replacement medications to tobacco users who were preparing to quit. The pre-intervention weighted average was 2.67 and the post-intervention weighted average was 4.67, representing a 75% increase. The largest negative percentage change was in regard to arranging follow-up for tobacco users who were preparing to quit. The pre-intervention weighted average was 2.33 and the post-intervention weighted average was 1.67, representing a 28% decrease. Appendix I shows a graphical display of the raw data for each questionnaire item.

Discussion

The data from the pre- and post-surveys from the staff in-service showed a greater familiarity with the 5 A's model and implementation plan as well as documentation and coding of tobacco use and dependence after the education given by the Project Director. It was clear that the staff already had a high level of familiarity with the harms of tobacco and the importance of treatment at baseline. The decision to use an in-service as the means of delivering the information for this project to the staff members proved to be effective; however, it posed a threat to the internal validity of this project in regard to selection bias. All staff members were invited to participate in the in-service; however, not all of the staff members were present to

receive the information. One of the six providers did not attend the in-service, although their questionnaire results measuring adherence to the 5 A's model was still factored into the final outcomes for this project due to the anonymity of the responses to the questionnaire rendering its omission impossible.

While provider adherence to the 5 A's model as measured by the pre- and post-intervention questionnaires did improve in some areas, the data does not support the original hypothesis that a structured, systems-based quality improvement project tailored towards the specific project sample setting would result in greater provider and clinic adherence to the 5 A's model. Results from the baseline assessment of the clinic's processes and workflow as well as the providers' self-reported adherence to the 5 A's model was consistent with the literature review in that adherence was higher for asking about tobacco use, advising tobacco users to quit, and assessing readiness to quit, but much lower for assisting patients in quitting and arranging for follow up (Tong et al., 2010; Tremblay et al., 2009; Williams et al., 2014).

The limitations of this project are due largely to the project design. The decision was made by the Project Director during the planning phase to evaluate provider adherence to the 5 A's model using a convenience sampling method rather than using patient data in order to preserve patient confidentiality and ensure project feasibility. This in turn led to a small sample size and possible attrition bias as the sample size went from $n=6$ before the intervention to $n=3$ after the intervention. This small sample size significantly limited the internal and external validity of the project. In addition to the small and unequal sample size, the most limiting factor of this project was the inability to match the providers before and after the intervention. Without being able to identify the matched pairs, a true and reliable comparison between the providers' adherence to the 5 A's model before and after the intervention could not be statistically analyzed.

with a high degree of power.

Conclusion

The results from this project as well as the literature in general highlight the fact that providers are not consistently delivering the full 5 A's model for the treatment of tobacco use and dependence (Tong et al., 2010; Tremblay et al., 2009; Williams et al., 2014). This presents a great opportunity for healthcare providers in a wide variety of settings to improve the care they give to their patients in this area. As long as tobacco use remains the leading preventable cause of death, disease, and disability in the U.S., aggressive measures should be taken to address it (Jamal et al., 2015; Siu, 2015; Williams et al., 2014). While the intervention in this project did not prove to have a significant effect on improving provider adherence to the 5 A's model, future study is not only warranted but vitally important.

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Appendix A

Figure 3. IRB Quality Improvement Determination Letter

The University of Kansas Medical Center

Human Research Protection Program

NOT HUMAN SUBJECTS RESEARCH DETERMINATION

May 24, 2017

Gregory Anderson
ganderson2@kumc.edu

Dear Gregory Anderson:

On 5/24/2017, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title:	Tobacco Cessation: A Quality Improvement Project Using the 5 A's Model
Investigator:	Gregory Anderson
IRB ID:	STUDY00141061
Funding:	None
Documents submitted for the above review:	<ul style="list-style-type: none"> • Letter to Providers • Greg Anderson Protocol

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required. Your project is determined to be quality improvement. Please ensure that any publications/presentations from this project note that it was undertaken as quality improvement.

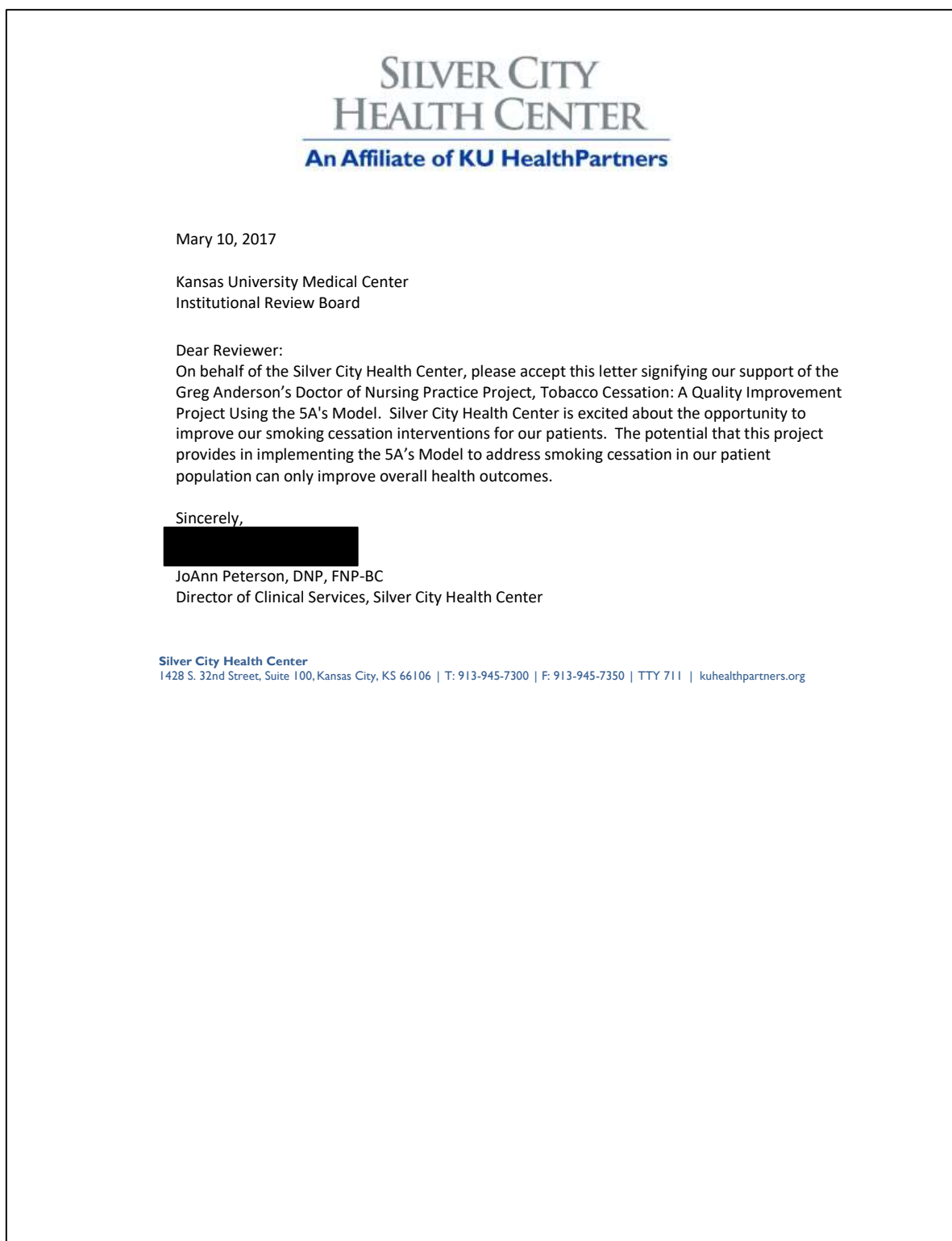
Sincerely,

Karen Blackwell

Mail-Stop 1032, 3901 Rainbow Blvd., Kansas City, KS 66160
Phone: (913) 588-1240 Fax: (913) 588-5771 humansubjects@kumc.edu

Appendix B

Figure 4. Letter of Permission from Project Site



Appendix C

Figure 5. Letter of Provider Consent

Dear Employee of Silver City Health Center,

My name is Greg Anderson and I am a family nurse practitioner student in the Doctor of Nursing Practice (DNP) program at the University of Kansas School of Nursing. I am contacting you because you are a provider at the Silver City Health Center and I wish to conduct my DNP project at your facility. I am recruiting participants for a quality improvement project focused on tobacco cessation. Participation involves completing a short anonymous survey about current practices regarding tobacco cessation. Following the survey, I will be implementing an intervention called the 5 A's model in the clinic. This model is considered the gold standard tobacco cessation guideline. A month after the intervention, I will administer the same survey to assess outcomes.

There are no personal benefits or risks to participating in this study. Participation is voluntary, and you can opt out of the project at any time. If you have any questions, please contact me by email at ganderson2@kumc.edu or by phone at (913) 579-2662. For questions about the rights of research participants, you may contact the KUMC Institutional Review Board (IRB) at (913) 588-1240 or humansubjects@kumc.edu.

Sincerely,

Greg Anderson

If you agree to participate in the project, please sign and date below:

Printed name: _____

Signature: _____

Date _____

Appendix D

Figure 6. Vital Signs Rooming Form

Pt. Name: _____	DOB _____	Age _____
REASON FOR VISIT: _____		ALLERGIES: _____
Ht. _____ Wt. _____ BMI _____ EDU _____ PHQ _____ LMP _____ BC _____		
T _____ BP: _____ / _____ Pulse _____ RR _____ O2 Sat: _____ % Pain level: _____ /10		
Last Pap: _____ Hx abnl Y/N _____ Last Dental: _____ Last Ophth: _____		
Last Mammo: _____ Hx abnl Y/N _____ CRC: _____ IFOB _____		
Tobacco use: <u>Never</u> <u>Former</u> <u>Current</u> Tobacco amount: _____ Ready to quit? <u>Y</u> / <u>N</u> / <u>NA</u>		
FBS/RBS: _____ A1C: _____ % Specialty since your last visit? _____		
Exercise: _____ Vac Due: <u>Tdap</u> <u>HepA</u> <u>HepB</u> <u>VAR</u> <u>MMR</u> <u>PPSV23</u> <u>PCV13</u> <u>HPV</u>		
<p>It is our practice to ask everyone about reading and working with numbers. Half of Americans have trouble with reading or using numbers. Es nuestra practica preguntar a todos acerca de leer y trabajar con numeros. La mitad de Americanos tienen dificultad con leer o usar numeros.</p> <p>Have you ever had a problem with reading or using numbers? Ha tenido problema con leer o usar numeros?</p> <p>Would you be interested in a program to help you improve your reading? Le interesaría un programa para ayudarlo a mejorar su lectura?</p>		

Original 3/18/17
S/SCHC/P&P 2016/Forms/Vital Signs rooming form 2017

Appendix E

Figure 7. Pharmacological Product Guide (AAFP, 2016).

PHARMACOLOGIC PRODUCT GUIDE: FDA-Approved Medications for Smoking Cessation

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS							VARENICLINE	
PRODUCT	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	BUPROPION SR		
	Nicorette [®] ZONNIC [®] Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint	Nicorette Lozenge, ¹ Nicorette Mini Lozenge, ¹ Generic OTC 2 mg, 4 mg, cherry, mint	Nicoderm CQ [®] Generic OTC (Nicoderm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hr release)	Nicotrol NS [®] Rx Metered spray 10 mg/mL aqueous solution	Nicotrol Inhaler [®] Rx 10 mg cartridge delivers 4 mg inhaled vapor	Zyban [®] Generic Rx 150 mg sustained-release tablet	Chantix [®] Rx 0.5 mg, 1 mg tablet	
	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy[†] and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy[†] and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy[†] (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Pregnancy[†] (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy[†] (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Concomitant therapy with medications/conditions known to lower the seizure threshold Hepatic impairment Pregnancy[†] (category C) and breastfeeding Adolescents (<18 years) <p>WARNING:</p> <ul style="list-style-type: none"> BLACK-BOXED WARNING for neuropsychiatric symptoms[§] <p>CONTRAINDICATIONS:</p> <ul style="list-style-type: none"> Seizure disorder Concomitant bupropion (e.g., Wellbutrin) therapy Current or prior diagnosis of bulimia or anorexia nervosa Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors (e.g., linezolid, methylene blue) 	<ul style="list-style-type: none"> Severe renal impairment (dose adjustment is necessary) Pregnancy[†] (category C) and breastfeeding Adolescents (<18 years) <p>WARNING:</p> <ul style="list-style-type: none"> BLACK-BOXED WARNING for neuropsychiatric symptoms[§] 	
PRECAUTIONS								
DOSING	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1-6: 1 piece q 1-2 hours</p> <p>Weeks 7-9: 1 piece q 2-4 hours</p> <p>Weeks 10-12: 1 piece q 4-8 hours</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15-30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth before or during use No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1-6: 1 lozenge q 1-2 hours</p> <p>Weeks 7-9: 1 lozenge q 2-4 hours</p> <p>Weeks 10-12: 1 lozenge q 4-8 hours</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day Allow to dissolve slowly (20-30 minutes for standard; 10 minutes for mini) Nicotine release may cause a warm, tingling sensation Do not chew or swallow Occasionally rotate to different areas of the mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>≥ 10 cigarettes/day: 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p>≤ 10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8-10 weeks 	<p>1-2 doses/hour (8-40 doses/day) One dose = 2 sprays (one in each nostril; each spray delivers 0.5 mg of nicotine to the nasal mucosa)</p> <ul style="list-style-type: none"> Maximum ~5 doses/hour or ~40 doses/day For best results, initially use at least 8 doses/day Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3-6 months 	<p>6-16 cartridges/day Individualize dosing; initially use 1 cartridge q 1-2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe Open cartridge retains potency for 24 hours No food or beverages 15 minutes before or during use Duration: 3-6 months 	<p>150 mg po q AM x 3 days, then 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Begin therapy 1-2 weeks prior to quit date Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Dose tapering is not necessary Duration: 7-12 weeks, with maintenance up to 6 months in selected patients 	<p>Days 1-3: 0.5 mg po q AM</p> <p>Days 4-7: 0.5 mg po bid</p> <p>Weeks 2-12: 1 mg po bid</p> <ul style="list-style-type: none"> Begin therapy 1 week prior to quit date Take dose after eating and with a full glass of water Dose tapering is not necessary Dosing adjustment is necessary for patients with severe renal impairment Duration: 12 weeks; an additional 12-week course may be used in selected patients 	

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS						
ADVERSE EFFECTS	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	BUPROPION SR
	<ul style="list-style-type: none"> • Mouth/jaw soreness • Hiccups • Dyspepsia • Hypersalivation • Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> - Lightheadedness - Nausea/vomiting - Throat and mouth irritation 	<ul style="list-style-type: none"> • Nausea • Hiccups • Cough • Heartburn • Headache • Flatulence • Insomnia 	<ul style="list-style-type: none"> • Local skin reactions (erythema, pruritus, burning) • Headache • Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> • Nasal and/or throat irritation (hot, peppery, or burning sensation) • Rhinitis • Tearing • Sneezing • Cough • Headache 	<ul style="list-style-type: none"> • Mouth and/or throat irritation • Cough • Headache • Rhinitis • Dyspepsia • Hiccups 	<ul style="list-style-type: none"> • Insomnia • Dry mouth • Nervousness/difficulty concentrating • Nausea • Dizziness • Constipation • Rash • Seizures (risk is 0.1%) • Neuropsychiatric symptoms (rare; see PRECAUTIONS)
ADVANTAGES	<ul style="list-style-type: none"> • Might serve as an oral substitute for tobacco • Might delay weight gain • Can be titrated to manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> • Might serve as an oral substitute for tobacco • Might delay weight gain • Can be titrated to manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> • Once-daily dosing associated with fewer adherence problems • Of all NRT products, its use is least obvious to others • Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours 	<ul style="list-style-type: none"> • Can be titrated to rapidly manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> • Might serve as an oral substitute for tobacco • Can be titrated to manage withdrawal symptoms • Mimics hand-to-mouth ritual of smoking • Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> • Twice-daily oral dosing is simple and associated with fewer adherence problems • Offers a different mechanism of action for patients who have failed other agents
DISADVANTAGES	<ul style="list-style-type: none"> • Need for frequent dosing can compromise adherence • Might be problematic for patients with significant dental work • Proper chewing technique is necessary for effectiveness and to minimize adverse effects • Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> • Need for frequent dosing can compromise adherence • Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> • When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms • Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis) 	<ul style="list-style-type: none"> • Need for frequent dosing can compromise adherence • Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic • Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease 	<ul style="list-style-type: none"> • Need for frequent dosing can compromise adherence • Cartridges might be less effective in cold environments (<50°F) 	<ul style="list-style-type: none"> • Seizure risk is increased • Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) • Patients should be monitored for potential neuropsychiatric symptoms (see PRECAUTIONS)
COST/DAY ⁶	2 mg or 4 mg: \$190-\$3.70 (9 pieces)	2 mg or 4 mg: \$2.66-\$4.10 (9 pieces)	\$1.52-\$3.48 (1 patch)	\$6.09 (8 doses)	\$10.37 (6 cartridges)	\$2.58-\$7.87 (2 tablets)

¹ Marketed by GlaxoSmithKline.

² Marketed by Nicotex USA (a subsidiary of Reynolds American, Inc.).

³ Marketed by Phizer.

⁴ The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and the ethical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

⁵ In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a health care provider immediately if they experience agitation, depressed mood, or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve.

⁶ Wholesale acquisition cost from Red Book Online. Thomson Reuters, January 2016.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (nonprescription product); Rx, prescription product.

For complete prescribing information and a comprehensive listing of warnings and precautions, please refer to the manufacturers' package inserts.

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Appendix F

Figure 8. Strategies for Motivational Interviewing (Fiore et al., 2008).

Express empathy.	<ul style="list-style-type: none"> • Use open-ended questions to explore: <ul style="list-style-type: none"> – The importance of addressing smoking or other tobacco use (e.g., "How important do you think it is for you to quit smoking?") – Concerns and benefits of quitting (e.g., "What might happen if you quit?") • Use reflective listening to seek shared understanding: <ul style="list-style-type: none"> – Reflect words or meaning (e.g., "So you think smoking helps you to maintain your weight.>"). – Summarize (e.g., "What I have heard so far is that smoking is something you enjoy. On the other hand, your boyfriend hates your smoking, and you are worried you might develop a serious disease.>"). • Normalize feelings and concerns (e.g., "Many people worry about managing without cigarettes.>"). • Support the patient's autonomy and right to choose or reject change (e.g., "I hear you saying you are not ready to quit smoking right now. I'm here to help you when you are ready.>").
Develop discrepancy.	<ul style="list-style-type: none"> • Highlight the discrepancy between the patient's present behavior and expressed priorities, values, and goals (e.g., "It sounds like you are very devoted to your family. How do you think your smoking is affecting your children?"). • Reinforce and support "change talk" and "commitment" language: <ul style="list-style-type: none"> – "So, you realize how smoking is affecting your breathing and making it hard to keep up with your kids." – "It's great that you are going to quit when you get through this busy time at work." • Build and deepen commitment to change: <ul style="list-style-type: none"> – "There are effective treatments that will ease the pain of quitting, including counseling and many medication options." – "We would like to help you avoid a stroke like the one your father had."
Roll with resistance.	<ul style="list-style-type: none"> • Back off and use reflection when the patient expresses resistance: <ul style="list-style-type: none"> – "Sounds like you are feeling pressured about your smoking." • Express empathy: <ul style="list-style-type: none"> – "You are worried about how you would manage withdrawal symptoms." • Ask permission to provide information: <ul style="list-style-type: none"> – "Would you like to hear about some strategies that can help you address that concern when you quit?"
Support self-efficacy.	<ul style="list-style-type: none"> • Help the patient to identify and build on past successes: <ul style="list-style-type: none"> – "So you were fairly successful the last time you tried to quit." • Offer options for achievable small steps toward change: <ul style="list-style-type: none"> – Call the quitline (1-800-QUIT-NOW) for advice and information. – Read about quitting benefits and strategies. – Change smoking patterns (e.g., no smoking in the home). – Ask the patient to share his or her ideas about quitting strategies.

Appendix G

Figure 9. Staff In-service Pre- and Post-Survey

Tobacco Cessation: A Quality Improvement Project Using the 5 A's Model

Pre-Survey

1. How familiar are you with the harms of tobacco and the importance of addressing tobacco use and dependence?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar
2. How familiar are you with the 5 A's Model for Tobacco Cessation?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar
3. How familiar are you with the plans to implement the 5 A's model at Silver City Health Center?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar
4. How familiar are you with documentation and coding as it relates to treatment of tobacco use and dependence?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar

Post-Survey

1. How familiar are you with the harms of tobacco and the importance of addressing tobacco use and dependence?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar
2. How familiar are you with the 5 A's Model for Tobacco Cessation?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar
3. How familiar are you with the plans to implement the 5 A's model at Silver City Health Center?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar
4. How familiar are you with documentation and coding as it relates to treatment of tobacco use and dependence?
 - a. Very familiar
 - b. Somewhat familiar
 - c. Slightly familiar
 - d. Not at all familiar

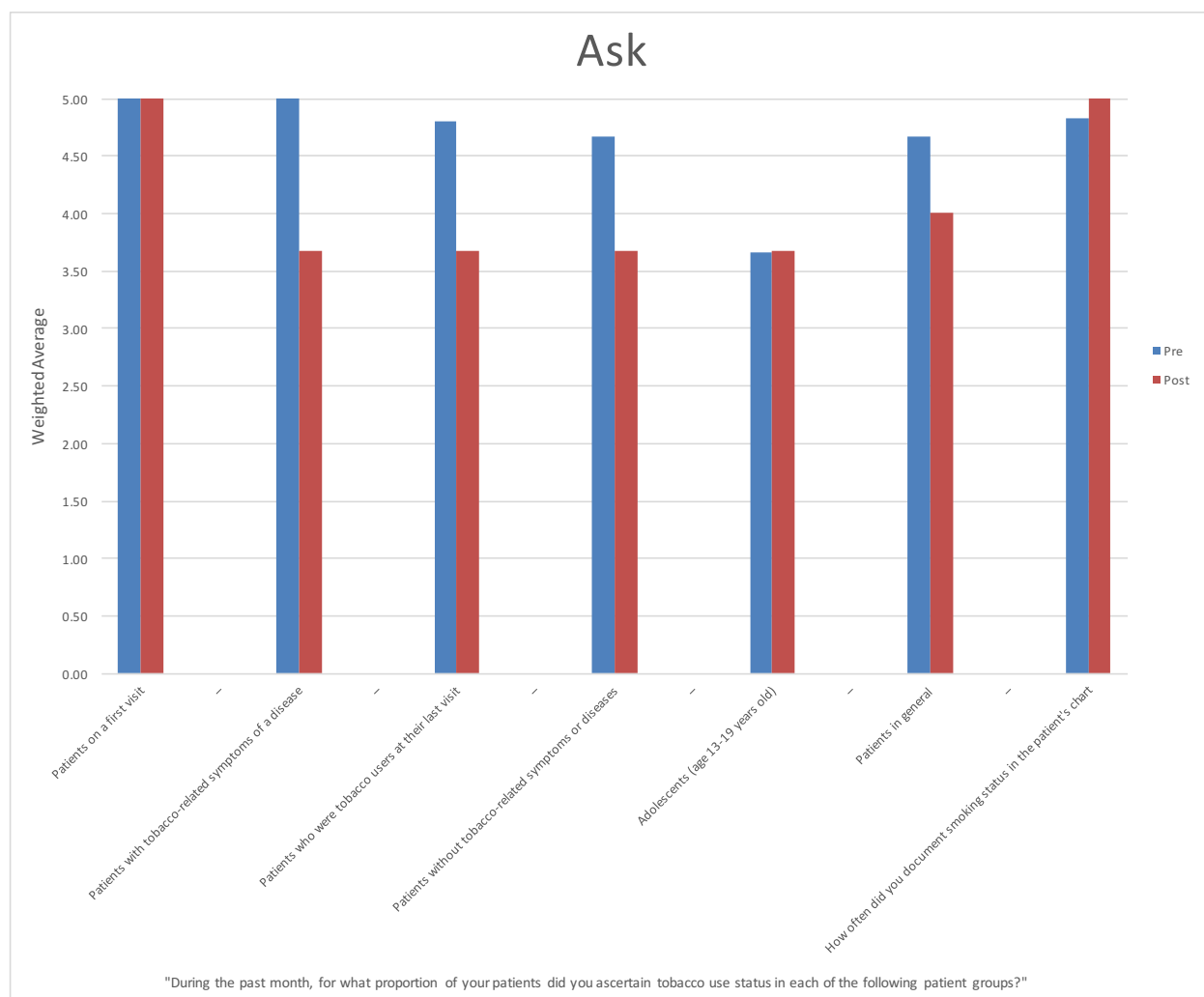
Appendix H

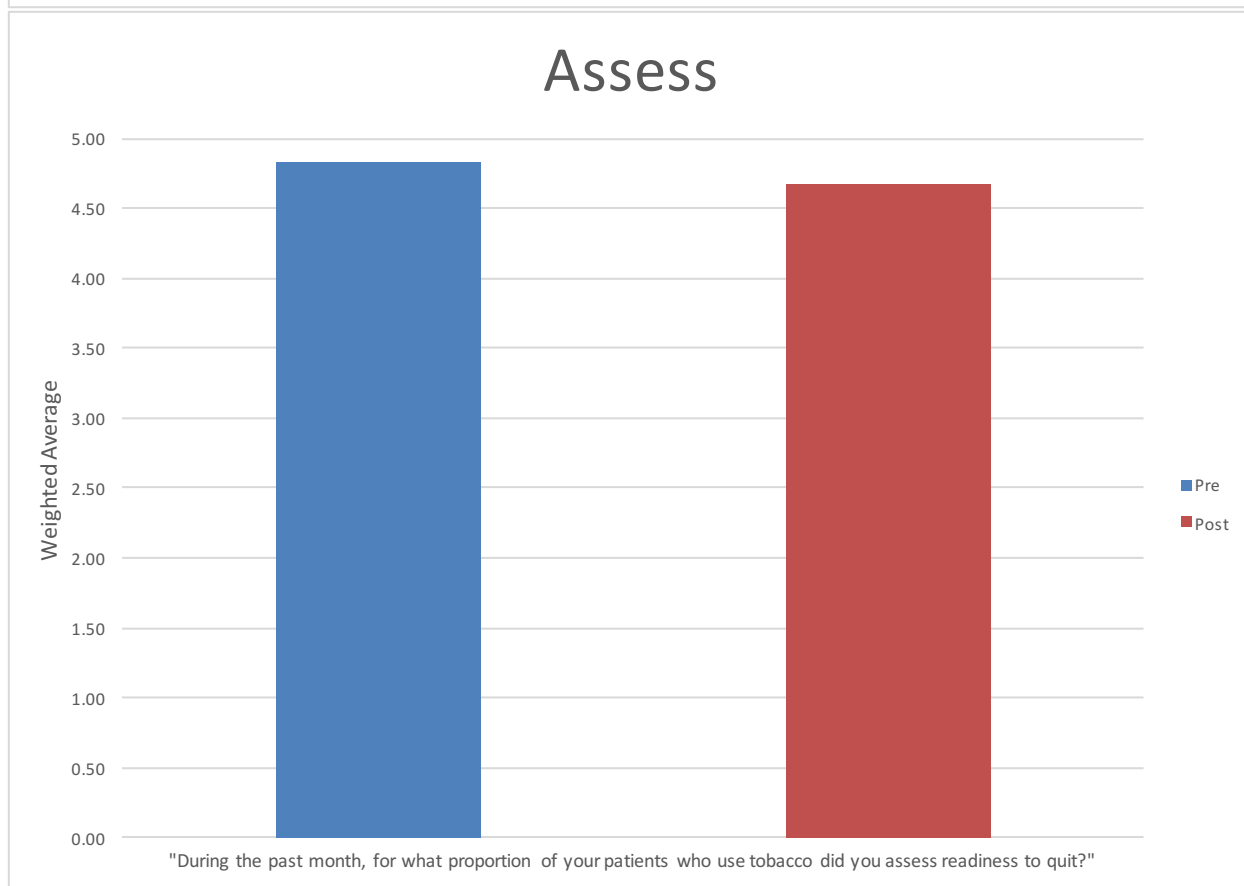
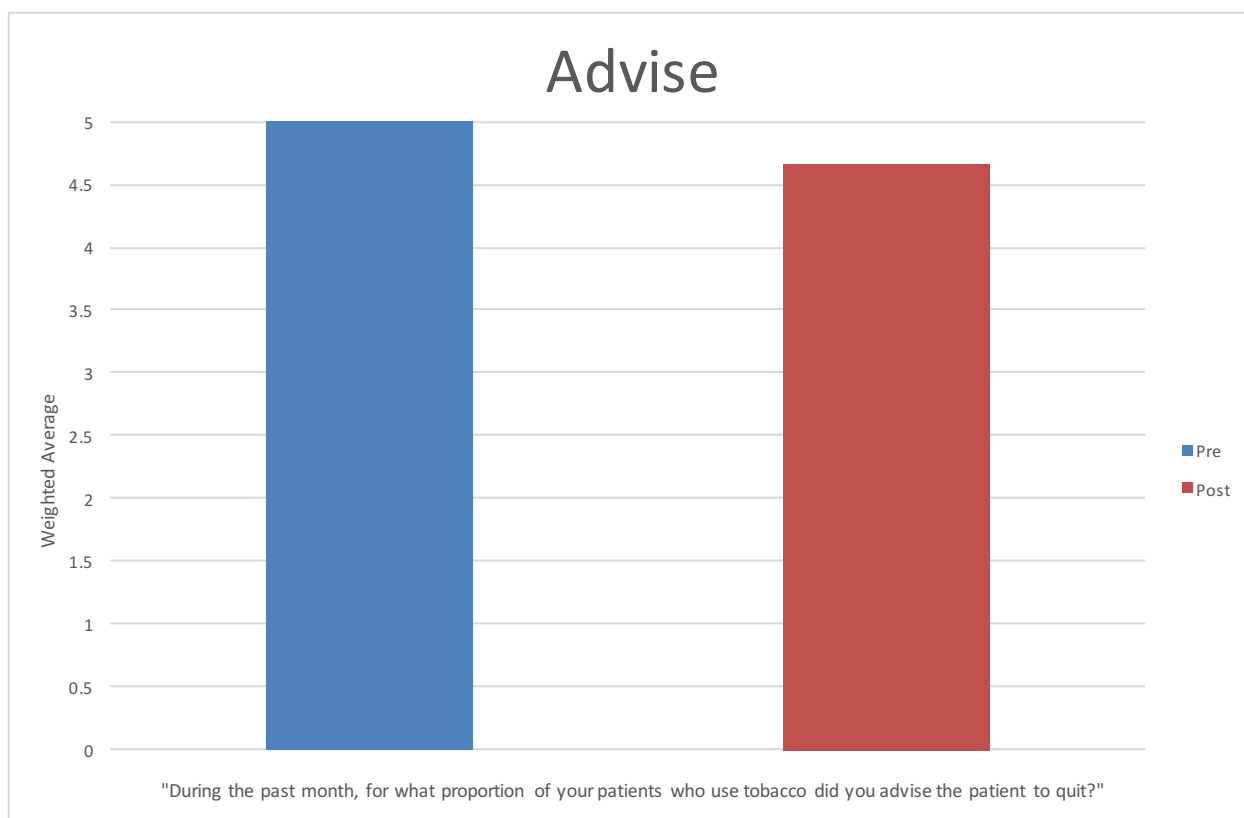
Figure 10. 5 A's Questionnaire (Tremblay et al., 2009). Adapted with permission.

5 A's Model for Tobacco Cessation Provider Questionnaire					
	all/almost all	more than half	about half	less than half	few/none
Ask					
During the past month, for what proportion of your patients did you ascertain tobacco use status in each of the following patient groups:					
a. Patients on a first visit					
b. Patients with tobacco-related symptoms of a disease					
c. Patients who were tobacco users at their last visit					
d. Patients without tobacco-related symptoms or diseases					
e. Adolescents (age 13-19yrs)					
f. Patients in general					
g. How often did you document smoking status in the patients chart					
Advise					
During the past month, for what proportion of your patients who use tobacco did you advise the patient to quit?					
Assess					
During the past month, for what proportion of your patients who use tobacco did you assess readiness to quit?					
Assist (Ready to quit)					
During the past month, for what proportion of patients who use tobacco and who were preparing to quit did you:					
a. Ascertain the amount of tobacco used per day					
b. Discuss previous quit attempts					
c. Discuss withdrawal symptoms					
d. Discuss worries about cessation					
e. Discuss strategies to quit tobacco					
f. Advise setting a quit date					
e. Recommend/prescribe nicotine replacement medications					
Assist (Not ready to quit)					
During the past month, for what proportion of patients who use tobacco and who were not ready to quit did you:					
a. Discuss the effects of tobacco use on health					
b. Discuss their perceptions of the pros and cons of using tobacco					
c. Discuss their perceptions of the pros and cons of quitting					
d. Express concerns about their tobacco use					
e. Discuss the effects of secondhand smoke on the health of relatives and friends					
Arrange (Ready to quit)					
During the past month, for what proportion of your patients who use tobacco and who were preparing to quit did you arrange an appointment or telephone call 1-2 weeks after the quit date?					
During the past month, for what proportion of your patients who use tobacco and who were preparing to quit did you refer to a tobacco cessation resource in the community such as KanQuit?					
Arrange (Not ready to quit)					
During the past month, for what proportion of your patients who use tobacco and who were not ready to quit did you arrange an appointment specifically to discuss quitting?					

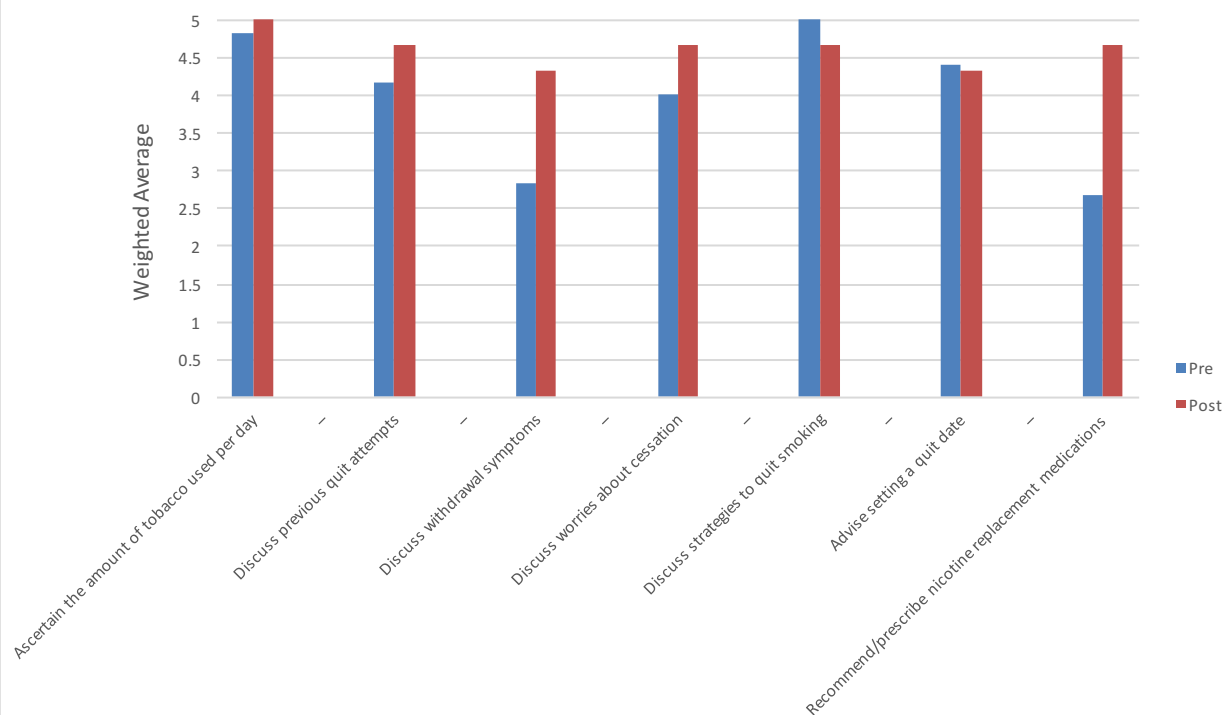
Appendix I

Raw Provider Questionnaire Data



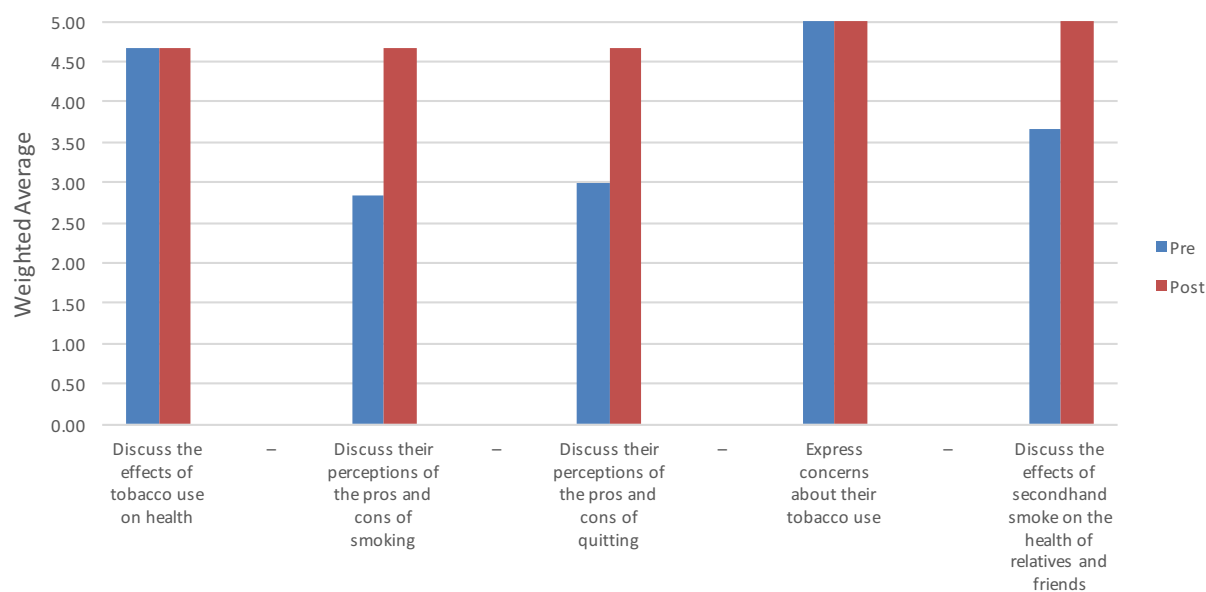


Assist: Preparing to Quit



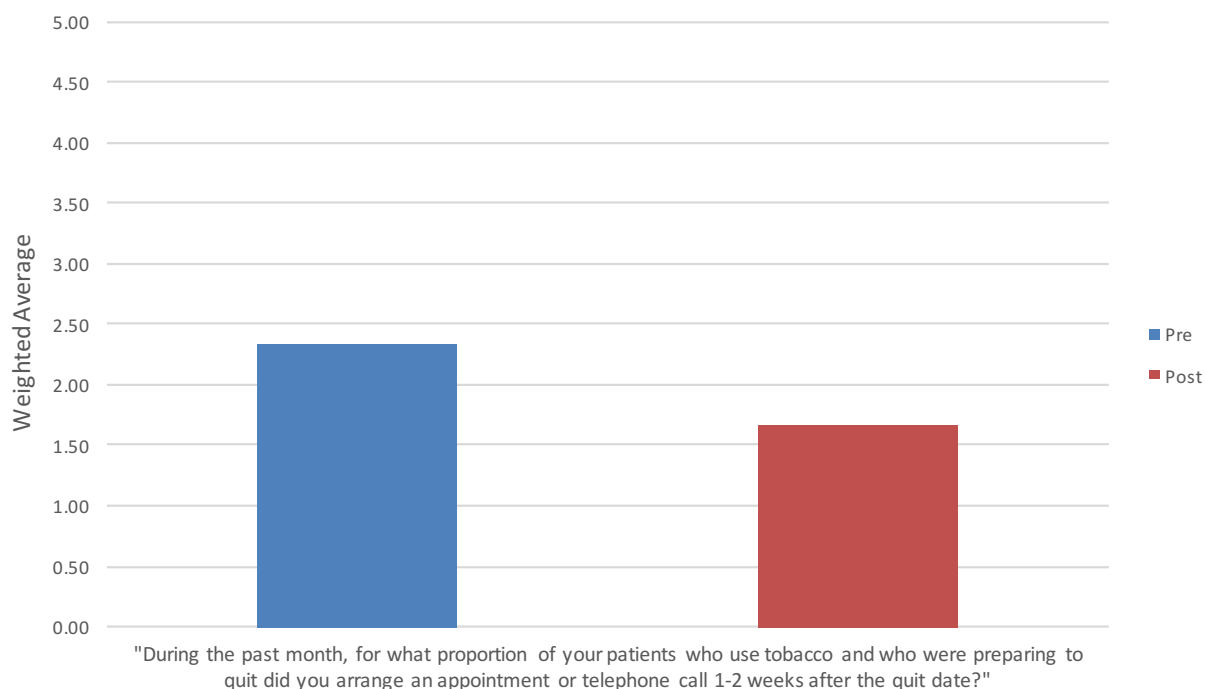
"During the past month, for what proportion of patients who use tobacco and who were preparing to quit did you:"

Assist: Not Ready to Quit



"During the past month, for what proportion of patients who use tobacco and who were not ready to quit did you:"

Arrange: Preparing to Quit



Arrange: Preparing to Quit Referral to Quitline

